PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : G06F 159/00 — A1

(11) International Publication Number: **WO 95/26009**

(43) International Publication Date: 28 September 1995 (28.09.95)

(21) International Application Number: PCT/US95/03655

(22) International Filing Date: 21 March 1995 (21.03.95)

(30) Priority Data:
08/210,901 21 March 1994 (21.03.94) US

(71) Applicant: IBV TECHNOLOGIES, INC. [US/US]; Suite 208, 1500 Westlake Avenue N, Seattle, WA 98109 (US).

(72) Inventor: ROBERTSON, George; Suite 1030, 2025 First Avenue, Seattle, WA 98121 (US).

(74) Agent: DWYER, Patrick, Michael; 1601 One Union Square, Seattle, WA 98101 (US).

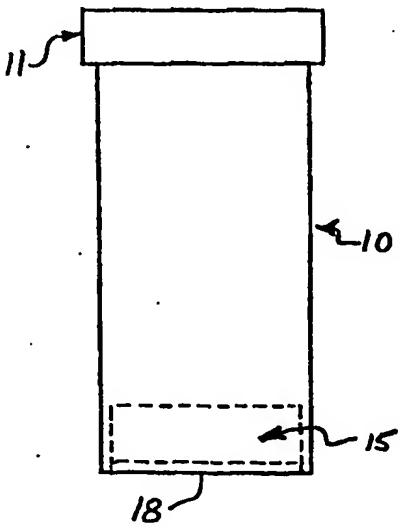
(81) Designated States: AM, AU, BB, BG, BR, BY, CA, CN, CZ, EE, FI, GE, HU, JP, KG, KP, KR, KZ, LK, LR, LT, LV, MD, MG, MN, MX, NO, NZ, PL, PT, RO, RU, SI, SK, TJ, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.

(54) Title: PROGRAMMABLE VOICE INSTRUCTED MEDICATION DELIVERY AND OUTCOMES MONITORING SYSTEM

(57) Abstract

A method (figure 3) and apparatus (figure 2) for a system that warns a prescription medicine patient when to take a medication, reminds the patient of the dosage and any other information important to correct dosage and non-interference with effectiveness of the medication, both by human voice messages (101), and records and stores when the patient took each dose. In addition the system also provides for both particularized erasable programming (20) of the patient unit (10) with dosage and voice instructions, and downloading and graphical processing of the unit's programming and compliance data by a pharmacist or home care professional. The system of the invention is integrated into the existing pharmacy system (500) through an interface (536).



Title: PROGRAMMABLE VOICE INSTRUCTED MEDICATION DELIVERY

AND

OUTCOMES MONITORING SYSTEM

TECHNICAL FIELD

The invention relates to dispensing prescription medication and monitoring outcomes for therapeutic medication regimes; more particularly, it relates to method and apparatus for a programmable voice instructed medication delivery and compliance monitoring system.

BACKGROUND

Each day tens of millions of Americans do not follow their doctors instructions for taking prescription medication. The cost of this noncompliance is estimated at one hundred billion dollars annually, and is second only to the illegal use of narcotics as the most costly drug problem facing our country. Expenditures relative to noncompliance represent avoidable health care cost - needless doctor visits, unnecessary hospitalization and medical procedures, and insurance claims for needless deaths. In a reformed health care system

focused on outcomes management, the skills of the pharmacist must become a fulcrum point for improving patient health by managing therapeutic outcomes. To effectively manage outcomes the pharmacist must have accurate patient compliance information. If a physician does not know how patients are actually using the medication, how can she properly manage outcomes or know, in fact, if the medication is working or should be changed?

Drugs are not effective unless taken properly. Everyone is noncompliant at some point their therapy regimen, whether chronic or acute care patients. If outcomes are to be managed, information that measures the therapeutic benefit of a drug is critical. Payors must know how improper dosing affects outcomes and impacts unnecessary downstream costs, in order to properly manage the cost of health care. Noncompliant patients produce billions of dollars in avoidable downstream health care cost. It is reported that five to ten percent of all hospitalizations, and 10% of all nursing home admissions are due to noncompliance.

"If I miss a pill or two, does it really matter?" Ask your pharmacist or physician. What about the "at risk" patient? Does it make a difference for the patient who has just had a major organ transplant? Most likely it does, so much so that the leading cause of a second transplant is noncompliance with transplant drug therapy regimens. While this may be the extreme, noncompliance also affects the diabetic, the heart patient, patients with mental disorders, asthma patients (especially children), chronic bronchitis patients and many other at risk patient populations. Noncompliant patients also include those who are otherwise healthy but are on antibiotics to cure an infection. Drug resistant species of otherwise readily medicable pathogens are created *in situ* in many instances of such improper dosing.

Identifying the most at risk patient populations for therapeutic failures which result in health complications due to noncompliance is the primary step in managing outcomes. In order to manage therapeutic outcomes, more

information is necessary. How can compliance with drug therapy be measured? Currently, pill counts, blood levels and patient interviews are the common methodologies employed. There are problems with all these methods, so no standard currently exists. Noncompliance remains a problem in health care. Since there is no established standard many good ideas are discussed but action is seldom taken. Any accurate measure of compliance or noncompliance must include patient self dosing information.

Over one half of the two billion prescriptions filled by pharmacists in the U.S. last year were paid for by third party payors, with the expectation that many of the prescriptions dispensed would potentially reduce the downstream cost of treating a more serious disease, state or condition and prevent unnecessary physician visits, hospitalization or other more expensive treatments. This number is expected to reach 65% by 1996.

Treatment of these health problems often requires close compliance with relatively complex medication regimes. It is not unusual for a person having one of the above health problems to be taking four or more different prescription drugs at one time. These drugs often differ significantly in dosages, both as to time and amount, as well as in their intended physiological effects. These drugs also often differ in the severity of potentially adverse reactions due to mismedication.

A plethora of prescription reminder gimmicks exist as evidence of the long standing problem of dosage compliance. Patients on medication typically have a problem remembering when and how often to take, or dose, their medication. And after the fact, seldom can report with any reliability when and how much they took. In the future of national and even world wide health care management, it is well recognized that dosage compliance is a critical issue. For some patients, the issue is of life and death magnitude.

When a physician prescribes medication in a non-hospital setting or when an over-the-counter medication is sold, substantial reliance is placed on

the patient to comply with the dosing instructions. Unfortunately, even in the case of acute illness, patient compliance with the prescribed dosing regimen is often casual or negligent. This problem, as it is exhibited even among maximally motivated patients suffering from a disease as serious as glaucoma with associated loss of sight, has recently been discussed. It has been pointed out that a substantial fraction of the patients took less than one half their required doses of sight-saving medication, that virtually all of the patients reported that they took all of their doses and that the prescribing physicians were completely unable to accurately identify those patients who were not taking their medication! This failure to properly self-medicate can lead to inaccurate feedback to persons monitoring the patient's progress and misinformation regarding the effectiveness of the drug. Similarly, the dosing regimen initially set is often inflexible and not designed to be easily modified to correspond to changes in the patient's condition.

If health care is dispensing drugs to effect a cure, it is important to know how patients take their drugs. A comprehensive compliance system which prompts a patient with an alarm to take a pill, gives appropriate counseling messages by voice, and records self dosing patterns is necessary to provide information to health care providers to ensure improved outcomes management.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the invention to provide a comprehensive compliance system which prompts a patient with an alarm to take a pill, gives appropriate counseling messages by voice, and records self dosing patterns is necessary to provide information to health care providers to ensure improved outcomes management.

It is a further object of the invention to provide an outcomes monitoring system that gives doctors and pharmacists thorough, easily recorded, readily processable, accurate and complete patient compliance information.

It is another object of the invention to provide an outcomes monitoring system that allows doctors and pharmacists to do a better job of monitoring drug use to manage therapeutic outcomes, and that can save lives and health care industry dollars.

It is another object of the invention to provide an outcomes monitoring system that allows the pharmacist to use her skills more effectively and that also provides documented proof of patient counseling on prescription drug usage.

It is yet another object of the invention to meet any or all of the needs summarized above.

These and such other objects of the invention as will become evident from the disclosure below are met by the invention disclosed herein.

The invention addresses and provides such a system. The invention represents the first drug therapy outcomes management tool designed for integration into the retail pharmacy work place, and is integrated into the existing pharmacy system through an interface. The invention provides information to the pharmacist in the practice setting which will allow the pharmacist to work directly with patients in managing drug therapy outcomes. A major component of the system is a vial which is programmed at the pharmacy. The vial is placed in a programmer, which resides on the pharmacy counter and serves as a Pharmacy PC to Vial Disk interface), and is programmed with the time of day for taking a pill (which is typically signaled by an alarm). The vial is set up for time stamping on a real time basis, with the shutting off of the alarm as the inferred time of intake of medication, then delivering a vocal message to the patient which tells them how to take the

medicine, and giving a significant counseling message such as a drug-food interaction precaution. The highly compact vial and its disk are both part of a system that includes software for integrating the system into any existing pharmacy customer service operation.

The vial with its electronic disk is patient centered for maximum reliability and ease of use - there is nothing for the patient to remember (except possibly not to lose the vial) as everything is prompted and instructed by easy to understand spoken instructions tailored to the patient and her medication. The vial is small enough to be held in the palm of the hand or carried on the person at all times or left accessible on the bed stand at night. There are no operating instructions beyond "push the button when the alert sounds and take the medicine as the voice instructs you". Optionally, the patient can even check the spoken instructions in advance of an alert or several times just after to review the dosage information or to insure understanding of the instructions, all without entering false compliance data.

Application of the invention to therapeutic outcomes management is especially beneficial in that the invention is the only system that effectively provides information necessary to manage therapeutic outcomes. It includes the first of its kind pill bottle which alerts the patient with an alarm reminder and instructs the patient with human speech to take the medication in strict accordance with the doctor's prescription, and allows the pharmacist to counsel the patient on proper use of each drug with a personalized voice recording each time the patient takes a pill. It is believed that this speech aspect alone will have an enormous positive impact on drug dosing compliance, over existing systems. When a patient regularly hears a competent voice, the incidence of misdosing or missing doses should drop significantly.

In order to manage outcomes, providers must have self dosing information and the capability to interpret dosing information to ensure improved drug utilization by patients. Given that the new health care system,

whether it is managed care, managed competition, or single payor, will be outcomes based; that prescription drugs represent the least expensive, most effective sure, when properly utilized; that two billion prescriptions were filled in the U.S. in 1993; health care professionals and administrators must ask themselves if we do not know how patients self dose, how can we properly manage therapeutic outcomes?

The invention records a complete history of the patient's use of the prescribed medications (through the use of one vial for each medication). The patient's activity in compliance with dosage times, dates, and frequency of use is encoded on a tiny microchip on a disk in the base of the vial for later retrieval by the pharmacist's PC when the patient returns the vial. The PC can then display an instant analysis and graphical report to the patient on how well the patient is complying with the prescribed drug regimen. The pharmacist then has patient dosing information on file that is critical for appropriate compliance counseling and potential modification of the therapeutic regimen in light of the actual dosing.

The invention will also assist those who need help in reading labels or instructions on consumer products or who are taking medication to have prescription instructions vocally rather than reading a label. Since the instructions from the disk are repeated by a simple touch of the vial, persons who have special needs such as blindness or old age related disorders with sight or memory impairments can have reassuring and reliable information at a touch.

For pharmaceutical applications, the pharmacist would insert a disk equipped vial into the programming unit. The disk would then be programmed with medication appropriate specific instructions, for example "take one pill with milk three times daily until all used". The pharmacist would then program any additional pertinent information such as dosage and download onto the disk by "burning" information into the disk's chip memory.

The major components are a ROM chip and a circuit board. The disk is battery powered and both switch and timer activated. It has a speaker that gives the verbal instructions which have been "burned" into memory (such as an EEPROM). The disk is preferably programmed via ultrasonic connection to the programmer, but may alternatively be programmed via wire plug-in (such as RS-232) to the programmer. When the pharmacist or other operator enters needed information into the computer, it can then be downloaded onto the disk.

The invention includes method and apparatus for a system that warns a prescription medicine patient when to take a medication, reminds the patient of the dosage and any other information important to correct dosage and non-interference with effectiveness of the medication, both by human voice messages, and records and stores when the patient took each dose. In addition the system also provides for both particularized erasable programming of the patient unit with dosage and voice instructions, and downloading and graphical processing of the unit's last programming and compliance data by a pharmacist or home care professional.

A preferred embodiment of the invention is a complete system comprising at least one base (pharmacy PC) system and one or more patient (vial/disk) systems. Each base system comprises software and hardware to program a patient unit with medication and prescription appropriate voice messages and an alarm plan tailored to suit the prescription there at the pharmacy. The base system software/hardware is also used to download both stored dosage compliance data and voice programming from a patient unit either at the pharmacy or at home with a mobile base unit. A base unit can download data and programming from a patient unit whether or not it was loaded by that base unit. The patient unit comprises a self contained programmable digital multi-alarm, digital-to-analog (DAC) voice playback circuitry, and time stamped dosage compliance memory storage, in a unit that

is preferably manufactured to be inserted into a specially provided recess in the bottom of an otherwise typical and widely used pharmacy type pill bottle. Alternatively, the unit may be manufactured as a short extension for attachment to a typical pill bottle.

The invention also provides a medication outcomes monitoring system with at least one base system in a pharmacy (on a PC) and a plurality of patient units. Each base system software and hardware to program a patient unit vial with medication and prescription appropriate speech and an alarm plan tailored to suit a patient. The system also has software and hardware to download stored dosage compliance data and most recent speech programming from a patient unit either at a pharmacy base system or at a home with a mobile base system. Any base system in the monitoring system can download data and programming from any patient unit that is compatible with the monitoring system, whether or not the patient unit was programmed by that particular base system. The outcomes monitoring system also has software and hardware to process and graphically display the stored dosage compliance data for comparison with a prescribed dosage plan and compliance counseling with a patient. The base system also has a programming unit for connecting a patient unit to the base system, and the programming unit has means to playback any speech stored in the patient unit.

The invention also encompasses an outcomes monitoring system with a multiple base units and multiple patient units, with base units in communication with a network of base units and in two way communication with one or more drug information databases and/or physician networks and/or national or regional health science information networks. Patient compliance information can be shared on the networks and stored in databases, and PIL and other current drug information can be transferred from a database to a patient unit.

The invention serves as a drug therapy compliance assistance and monitoring device. It puts voice transmitted information or speech into a patient unit such as a specialized medication container or vial for patients who have difficulty reading printed labels and for patients on critical drug regimens requiring strict dosage compliance. The system of the invention includes subsystems, such as an erasably programmable disk that fits into or onto the standard pharmaceutical vial from pharmacies, or into a special vial like a standard drug vial but with a special pocket or recess for the disk, preferably in the bottom of the vial. The system also includes programmer software and pharmacy interface software (which it is contemplated can be customized for different pharmacies and pharmacy data systems) running on a pharmacy or mobile PC (or other computer system). The system also includes a disk programmer unit that programs the voice messages into the disk. The programmer unit is preferably adapted to receive the base of the special vial containing the disk into a receptacle in the programmer unit. The programmer unit may be "dumb" or "smart". That is, it may serve as nothing more than a connector from the disk to the pharmacy computer, and perhaps have rudimentary UART componentry built in for facilitating the relaying of data to and from the disk (referred to as "dumb"), or it may include one or more of the hardware and software subsystems otherwise relegated to the pharmacy PC, together with sophisticated UART componentry (referred to as "smart").

In general, a disk is programmed at a pharmacy at the time a prescription is filled (and sometimes at a mobile PC carried by a visiting home health care professional) to sound an audible alert or alarm at each of the dosage times specifically prescribed by the physician. In addition to the prescription information, including dosage times and Patient Information Leaflet (referred to sometimes as PIL information), specific dosage information and instructions for taking the medication are uploaded or programmed onto the disk in the form of digitally stored speech. When the patient picks up the vial containing the

disk and manually (optionally automatically) activates a switch on the bottom of the vial to silence the alert, the preprogrammed spoken instructions are delivered by the disk. The device also records the time that the alert was silenced (or alternatively, the time of the message activation) as the inferred dosage time in the disk memory allocated to this compliance data. A pharmacy or physician can later download the compliance information from the disk back to the PC through the programmer unit when the patient completes the prescription and returns the vial to the pharmacy. At that time, the disk programming can remain unchanged (as for a simple refill), it can be modified to reflect counseling resulting from detected non compliance with the prescribed regimen, such as differently worded instructions or reminders, or it can be completely reprogrammed for a new prescription or even a new patient.

As memory storage becomes less expensive and smaller, it is contemplated that additional features such as automatic voice messages requesting the patient to better comply with the dosage times whenever the disk detects non-compliance (such as by comparison of the compliance data with the stored dosage time data) will be added to the system.

The preferred use for the disk is for medication containers, not only for blind patients or patients who can not easily read the labels or instructions, and for drugs requiring strict dosage compliance, but also generally for all prescription drug users to alleviate and remedy the kinds of serious system-wide problems noted above. It is believed that spoken reminders and instructions, specifically tailored to the individual patient and the particular prescribed medication, will significantly improve compliance across a wide spectrum of patient populations, especially for at risk patient populations. It is anticipated in addition that the device will also be useful in other applications such as manual or automatic delivery of spoken instructions, and monitoring usage or compliance for other consumer products.

Features of the system of the invention include alarms at times for medication dosage, spoken message giving medication name, dosage (number of pills or quantity to pour) and instructions, recording of actual dosage time for compliance information, optional spoken message instructing patient to refill prescription (further optionally naming a specific pharmacy, such as the one where the message was programmed), transfer of compliance data back to pharmacy or physician, and interface of collected information onto various medical information systems, such as regional or national compliance databases. Patient compliance data on such databases would include a drug/therapy classification and a specific compliance percentile ranking.

Preferably the voice data will be stored in memory as digitized voice data. When the disk is programmed, an incoming voice wave form (such as from a microphone) will be digitized and stored in erasable disk memory. Alternatively, wave forms prerecorded and stored in a PC may be used. As a further alternative, some or all of the voice data may be stored in analog form. Whenever the appropriate contact or switch on the disk is activated, or optionally at preprogrammed times or the occurrence of designated conditions, the stored voice data will be sequentially output to the disk speaker driver and amplification circuit. The disk may contain one stored message, or as many as memory will hold. In general, the same message will be played each time a particular switch is activated, or particular triggering event or condition occurs. The message length limit is presently about 20 seconds, but developments in compression and memory technology should result in the possibility of longer message length or greater number of messages stored.

In the programming mode the disk (and vial) will be connected to a programming module, which in turn may be connected to a PC or other computer for uploading prerecorded messages to the disk. In preferred embodiments, the disk will connect to the programming module through non-invasive ultrasonic contacts. Alternatively, the disk may connect through two

electrical contacts. The necessary software for recording and digitizing speech and processing the speech (including compression, filtering and the like), and for storage of the digitized speech in disk memory, is presently available to or within the skill of the artisan, though it is contemplated that some system developers practicing the invention will develop custom software to implement one or more of the necessary functions.

In the disk playback mode, a message will be played each time a switch is activated. The switch may be a small push button switch or may be as simple as two contacts that the user touches when the medicine container is picked up, or may be some other switch or detection means now known or later developed. Generally, once the message is given, it will not repeat until the switch is activated again.

To keep manufacturing cost as low as possible while retaining the programmability that is desired in the disk, it is contemplated that an IC or ASIC chip which incorporates some or all the features of the disk componentry will be developed for use in the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram for the major physical components of the preferred system.

Figure 2 is a block diagram of the PC programming station.

Figure 3 is a block diagram of voice programming logical functions.

Figure 4 is a block diagram of the functionality of the disk.

Figure 5 is a block diagram of information and data flow in the system of the invention.

Figure 6 is a front elevation of a prior art vial.

Figure 7 is a front elevation of the preferred vial of the invention.

Figure 8 is a schematic plan view of the disk of the invention.

Figure 9 is a schematic side view of the disk of the invention.

Figure 10 is a schematic side partial cut away elevation of the programmer unit of the invention.

BEST MODE OF CARRYING OUT THE INVENTION

Turning now to the drawings, the invention will be described in a preferred embodiment by reference to the numerals of the drawing figures wherein like numbers indicate like parts.

Figure 1 is a block diagram for the major physical components of the preferred system. PC programming station 100 transmits and receives and processes data from pharmacy mainframe computer(s) via link 200. It also sends data to and receives data from programming unit 20. Software is loaded and running as part of the existing pharmacy PC 100, and communicates with programming unit 20 to program disk 30 in vial 10.

Link to pharmacy computers 200 comprises drivers for each type or vendor of the various pharmacy information systems. Currently, pharmacy systems are running MS-DOS, UNIX, PICK and other operating systems. The drivers interface with the various operating systems and existing pharmacy software. Such drivers will be known to those skilled in the art or readily developed by them. The pharmacy computers referred to above may be other PC's or mainframes on site or within a particular pharmacy chain, or as part of a regional or national medical information system.

Figure 2 is a block diagram of the PC programming station or pharmacy base subsystem of the overall system of the invention. Programming unit 20 connects to the pharmacy PC programming station 100, and preferably uses its monitor 110 and keyboard 120. Programming station 100 preferably has attached microphone 130, playback speaker(s) 140 and interface to disk 30. Programming unit 20 may optionally have its own microphone and speakers,

either as separate peripheral components, or as integral components inside unit 20 (see Fig. 10). The system preferably includes a sound card 101 and I/O card 103 in the Pharmacy PC 100.

Sound card 101 in PC 100 is used to digitize and process speech for a message to be stored on disk 30. Software resident on card 101 or elsewhere loaded in PC 100 processes the digitized sound, performing filtering and dynamic range adjustment of the signals. The processed speech is then loaded into the disk through conventional ports on I/O card 103 in PC 100. Speakers optionally integrated into programmer unit 20 provide for playback of any loaded voice message for the purpose of message confirmation.

Figure 3 is a block diagram of voice programming logical functions. At voice input stage 310, a voice message is sampled a sound card in conjunction with a microphone to convert the signal from analog form to digital form. Optionally, input stage 310 may be intake of a prerecorded (previously sampled or synthesized) voice message. The message is then stored 320 either in PC 100 or in programmer 20 for post processing 330 (filtration, level adjustment, etc.). Once the voice message is processed, the digitized message can be loaded onto disk 30 at stage 340 through programming unit 20. Compliance data from disk 30 can also be downloaded at stage 350 to the programming unit 20 for a physician's usage.

Figure 4 is a block diagram of the functionality of disk 30 and depicts functions that may also be performed by a disk IC or ASIC 400. Such a disk IC integrates the functions of control, timers, speaker drivers and voice memory. Disk 30 includes microprocessor 50, timer 420, digital-to-analog (DAC) converter 40, speaker driver 410, EEPROM chip 35 for programmable speech storage, and optional memory chip 55 for optional permanent voice messages (ie, "Time to take your medication!"), all of which may be included in a custom IC 400. Disk 30 also includes amplifier 42 and voice transducer (speaker) 60, as well as battery 45, switch 65, I/O port 32, and optional

alternative compliance detector 440 (such as any of several compliance detection means now known in the art or later developed). An additional option is for disk 30 to include a patient alert light 38 to indicate to a hearing impaired patient that the speaker has activated and that it is time to take medication.

IC 400 may be built from a conventional low cost microcontroller or from complete custom non-programmable logic, as will be dictated by concerns known to those skilled in the art. Current technology is available in many forms to accomplish the disk voice function, and range from voice synthesis to stored speech. Stored speech consisting of sampled voice wave forms is preferred. Technology currently available in talking greeting cards and the like utilizing voice masked into read only memory (ROM) is low in cost. ROM stored speech would therefore be preferred for any messages that were standard and not required to be specific to the patient or the medication. For the other specific voice messages programmed for a particular patient and/or medication, either battery backed RAM (random access memory) technology or erasable programmable memory EEPROM is preferred over ROM.

Figure 5 is a block diagram of information and data flow in the overall outcomes management system of the invention. Retail pharmacy base system (PC station) 500 receives current drug data 524 from database 523. Base system 500 generates a patient profile 511 and sends it to 3rd party payor 512 (who also exchanges claim information 557 with base system 500). Pharmacy system 500 generates a prescription label 555, a PIL 556, and claims 558 and 557 (for processing with Payor 512). Doctor 533 writes Rx 534 which goes to Pharmacist 535. Pharmacist 535 puts Rx 534 into the system 500, generating (after analysis of patient compliance and other data) if necessary a precription change request 536. Base system 500 conveys dosage, PIL and other drug related data to programmer 541 (see also programmer 20 in Figs.

1, 2, and 10), for temporary storage or processing in data storage 543, or for relay to patient unit disk 542 (see also disk 30 in Figs. 1 and 8).

Figure 6 is a schematic representation of a standard pharmacy vial 1. In Figure 7, vial 10 has cap 11 and recess 15 in its base for receiving disk 30. Disk 30 is then covered with cover 18. Vial 10 is preferably from Owens Brockway, model T-20. A separately housed disk unit (not shown) may alternatively be ultrasonically welded to a standard vial to achieve vial 10. Required joint preparation and welding techniques will occur to those skilled in the art.

In Figures 8 and 9, a schematic representation of disk 30 has data I/O port 32, EEPROM 35, DAC 40, amplification electronics 42, battery 45, microprocessor 50, additional memory 55, speaker transducer 60, and input sensor switch 65.

Disk 30 executes at least the following instructions: receive voice information, medication schedule and correct time from programmer 20; access stored recorded voice information and play it; track real time for at least 2 months with at least 10 minute resolution; store medication schedule and alert patient when medication should be taken; upload compliance information to programmer 20 on command.

Estimated length of the stored message(s) is 20 to 30 seconds depending on the sampling and compression algorithms used and the amount of memory 35 that is incorporated onto disk 30. This should allow about 20 seconds of voice message for a "primary message" (typically instructions on dosage and PIL). This should leave space for a secondary message which instructs the patient to return to a (or the) pharmacy for a refill. Disk 30 or IC 400 has sufficient memory to store the following items: at least 20 seconds of recorded voice information; time of day and date; medication schedule; and compliance information.

Using a preferred 4 KHz sample rate with each sample being 4 bits of resolution requires about 60 K of memory for a 30 second message. About 1 K of memory additional memory is used to store the compliance schedule and record compliance usage by the patient. A microprocessor 50 provides the processing capability and requires about 1-2 K of RAM or ROM for program storage.

Disk 30 preferably has a preferred diameter of 30 mm, a maximum diameter of 34 mm, a preferred thickness of 12 mm and maximum thickness of 16 mm, though differently sized embodiments can always be accommodated at the expense of medication storage capacity in a custom vial 10. Disk 30 preferably snaps into the bottom of the custom vial 10 and is preferably removable only with the use of a custom extraction tool the design of which will be in accordance with factors known to the art.

Disk 30 may include disk IC 400 to provide some or all of its required functions. IC 400 may be a microcontroller or other custom logic device. IC 400 contains timer, I/O port electronics, memory, sensor input interface electronics, speaker drive electronics, crystal interface electronics and battery interface electronics.

Disk 30 or IC 400 outputs the voice information to speaker 60 when switch 65 is activated. The digitized speech data is output in a sequential manner. The speaker drive consists of digital to analog converter and drive amplifier. The resolution of the digital to analog converter is at least 4 bits. The speaker volume and frequency response are fixed with no user adjustments possible, and optimized for sound quality and battery life, as will be appreciated by those skilled in the art.

Disk 30 will have at least one input sensor 65. This sensor is preferably an activation switch which can be used by the patient to activate the voice information. The switch interfaces directly to disk 30 or IC 400 and signals microprocessor 50 to lead the voice information out to speaker 60.

In addition to activation switch 65 the disk also optionally has compliance detector 440 (such as one that detects when the bottle cap is removed). When cap 11 is removed the microprocessor 50 records the date and time in memory for a compliance record. This optional detector may also interface directly to IC 400.

Disk 30 is preferably programmed via ultrasonic connection to programmer 20. Alternatively, disk 30 communicates with programmer unit 20 through conventional serial port architecture. The I/O port 32 electronics are part of disk 30 or IC 400. A timer 420 in the form of a crystal or other oscillator drive is used to clock the disk electronics and to provide a basis for the alert and compliance timer.

Membrane speaker components with an adequate balance of voice quality and low cost are presently preferred. Current low cost products using piezoelectric disks for the speakers that tend to have poor sound quality due to the frequency response of the piezoelectric device will serve, but are not preferred at this time. However, it is an option to compensate the frequency response of the piezoelectric output device in the programming unit before the disk is programmed to thus enhance the disk's ability to use less expensive components. Another option for improving the reproduction quality is to use a very compact voice coil speaker, though this will have size and space trade offs. The disk requires its own electrical power, preferably two 3 volt batteries in one embodiment.

Preferred speakers for disk 30 are very small and thin while at the same time giving reasonable voice quality so that the message can be easily understood. Piezoelectric transducers are generally used for buzzers or alarms and not generally acceptable, except as noted above, though it is anticipated that they will improve and become available for practice with the invention. Small thin coil speakers are preferred. Other types of speaker transducers may be employed on the disk without departing from the scope of the invention.

In another embodiment a preferred voltage for the battery is 5 volts. However, different speakers require different drive voltages for the speaker, and the skilled artisan will readily discern the appropriate battery/speaker match up. The switch is preferably a membrane type switch which is mounted on the bottom of disk 30. Alternatively, the switch may incorporated as part of the housing in vial 10 or recess cover 18, with internal contacts being built onto the circuit board. Crystal speed for the timer may be 1 MHz or even less.

In Figure 10, a schematic partially cut away programming unit 20 connectable to PC station 100 by cable 21, has data I/O contacts 25 for connecting with disk 30 in vial 10 via disk I/O 32, as vial 10 is received into the illustrated recess in programmer 20. Optionally, programmer 20 has "smart" electronics pack 23 to enable it to perform some or all of the processing or programming functions otherwise left to PC station 100. As further options, programming unit 20 has transducer pack 28 (microphone and/or speaker), and control pack 27 (indicator lights and/or switches) for manually controlling some or all of the programming functions of programmer 20 when "smart" pack 23 is installed and in use.

Programming unit 20 provides an interface to disk 30 at the pharmacy in order for PC station 100 to program the voice messages into disk 30. PC station 100, via programmer 20, performs voice recording and storage, filtering of the voice information, dynamic range adjustment, and processing and programming of the resultant voice message into disk 30 memory 35. In embodiments employing a "smart" programmer, some of these functions may be handled directly on the programmer.

Any of several encoding methods will serve; however the current preference is for minimum memory usage which is effected with a 4 KHz sample rate with post processing filtering and dynamic range compensations, and a sample resolution of 4 bits.

The voice recording and post processing algorithm is important because it will also affect the amount of memory that is needed in disk 30 and the amount of processing power needed in programmer 20 or base PC station 100 (depending on whether "smart" or "dumb" programmer is employed). If the recording is done using less than 4 bits of resolution, then less memory is used in disk 30. If significant post processing is needed, then additional computing power may be necessary in base station 100 in order to achieve the post processing in a reasonable amount of time. A 486 PC is preferred at this time, though it can be an "SX" type machine. It should be equipped with a high speed 16550 UART in the I/O card to achieve desired rates of transfer between the base station 100 and programmer 20.

The exact filtering requirements for any given application may be determined experimentally, but there are several areas of filtering methods routinely applied to the digitally stored voice data, namely trimming of dead air at the start and end of the recording, amplitude adjustment to level the average volume over the entire recording, band width limiting of the recording, conversion of recording from 8 bits to 4 bits (alternatively 2-4 bits). This may be done on a logarithmic scale, rather than a linear scale. (DAC 40 on disk 30 can be used to decode the recorded data as a logarithmic scale.) In addition, frequency compensation for the particular speaker/enclosure design to optimizing speaker output.

Dynamic range compensation is used to scale the recorded message amplitude so that it fits within the 4 bits of resolution and to equalize the average volume of the message over the full length of the message, and to limit base frequencies in order to reduce power requirements. All dynamic range compensations are typically performed in PC station 100, and the dynamic range compensation is adequately handled by a 486 PC. Special purpose Digital Signal Processing (DSP) chips are becoming common on various sound

cards, and the processing power of such chips on a sound card in PC station 100 will have a beneficial impact on processing load on the 486 CPU.

Preferably all post processing occurs in the base station 100 or in programming unit 20 so that only playback is required in disk 30. The playback processing in disk 30 consists of decompression of the message file which is required when a compression algorithm is used to decrease the amount of memory required in disk 30. It is contemplated however that some post processing functions can be left for the disk 30 to do, given sufficient processing power on the disk and perhaps some additional memory, without departing from the scope of the invention.

Typically programmer 20 uses the file format appropriate for the sound board 101 for capturing data. In the PC world WAV and VOC files are common standards for digitized sound. If MS Windows is selected as a platform, WAV recording is fairly simple. The format of the recorded data can also be converted to other formats, if thought by those skilled in the art to be advantageous in the post processing stage 330.

With regard to software and hardware systems and components above referred to, but not otherwise specified or described in detail herein, the workings and specifications of such systems and components and the manner in which they may be used, both cooperatively with each other and with the other elements of the invention described herein to effect the purposes herein disclosed, are all well within the knowledge of those skilled in the art. Likewise with all circuitry, electronic components, speakers, and voice programming in general (including sampling, filtering and other processing, and storage with or without compression), above referred to, but not otherwise specified or described in detail herein, the workings and specifications of these aspects are all likewise well within the knowledge of those skilled in the art, and no concerted attempt to repeat here what is generally known to the artisan has therefore been made.

In compliance with the statute, the invention has been described in language more or less specific as to structural features. It is to be understood, however, that the invention is not limited to the specific features shown, since the means and construction shown comprise preferred forms of putting the invention into effect. The invention is, therefore, claimed in any of its forms or modifications within the legitimate and valid scope of the appended claims, appropriately interpreted in accordance with the doctrine of equivalents.

CLAIMS

I claim:

1. A medication container having means to alert a patient that a medication dosage is presently due to be taken by the patient, and further having means to erasably store programmable speech regarding patient and medication specific dosage amount and PIL data and to emit said speech in response to patient activation of a compliance detection means.

2. The apparatus of Claim 1 wherein said compliance detection means is comprised of a patient activated means to silence said means to alert and a means to note and store a present time and date whenever said means to alert is silenced.

3. The apparatus of Claim 1 wherein activation by the patient of said compliance detection means activates a means to note and store a present time and date without regard to whether said means to alert has been activated.

4. The apparatus of Claim 2 having memory means to store multiple recorded instances of time and date compliance data for uploading to a base system on request.

5. The apparatus of Claim 1 wherein said means to alert comprises means to store and emit speech to effect said alert.

6. The apparatus of Claim 5 wherein said speech to effect said alert is programmable.

7. The apparatus of Claim 4 further having means to upload to a base system all data stored in said apparatus.

8. An apparatus having means to alert a patient that a medication dosage is presently due to be taken by the patient, and further having means to erasably store programmable speech regarding patient and medication specific dosage amount and PIL data and to emit said speech in response to patient activation of a compliance detection means.

9. The apparatus of Claim 8 wherein said compliance detection means is comprised of a patient activated means to silence said means to alert and a means to note and store a present time and date whenever said means to alert is silenced.

10. The apparatus of Claim 9 having memory means to store multiple recorded instances of time and date compliance data for uploading to a base system on request, and means to upload to a base system all data and speech stored in said apparatus.

11. The apparatus of Claim 10 further having means to attach said apparatus to a prescription sized medication container.

12. The apparatus of Claim 10 in conjunction with a prescription sized medication container.

13. A medication outcomes monitoring system comprising at least one base system and a plurality of patient units, wherein each base system further comprises software and hardware to program a patient unit with medication and prescription appropriate speech and an alarm plan tailored to suit a patient.

14. The outcomes monitoring system of Claim 13 further comprising software and hardware to download stored dosage compliance data from a patient unit either at a pharmacy base system or at another location with a mobile base system.

15. The outcomes monitoring system of Claim 14 wherein any base system in said outcomes monitoring system can download data and programming from any patient unit that is compatible with said outcomes monitoring system, whether or not said patient unit was programmed by said base system.

16. The outcomes monitoring system of Claim 14 further comprising software and hardware to process and graphically display said stored dosage compliance data for comparison with a prescribed dosage plan and compliance counseling with a patient.

17. The outcomes monitoring system of Claim 13 wherein said base system further comprises a programming unit for connecting said patient unit to said base system, said programming unit having means to playback any speech stored in said patient unit.

18. An outcomes monitoring system having a plurality of base units and a plurality of patient units, wherein a base unit is in communication with a network of base units and in two way communication with at least one drug information database, whereby patient compliance information may be shared on said network and stored in said database, and PIL and other current drug information can be transferred from said database to a patient unit.

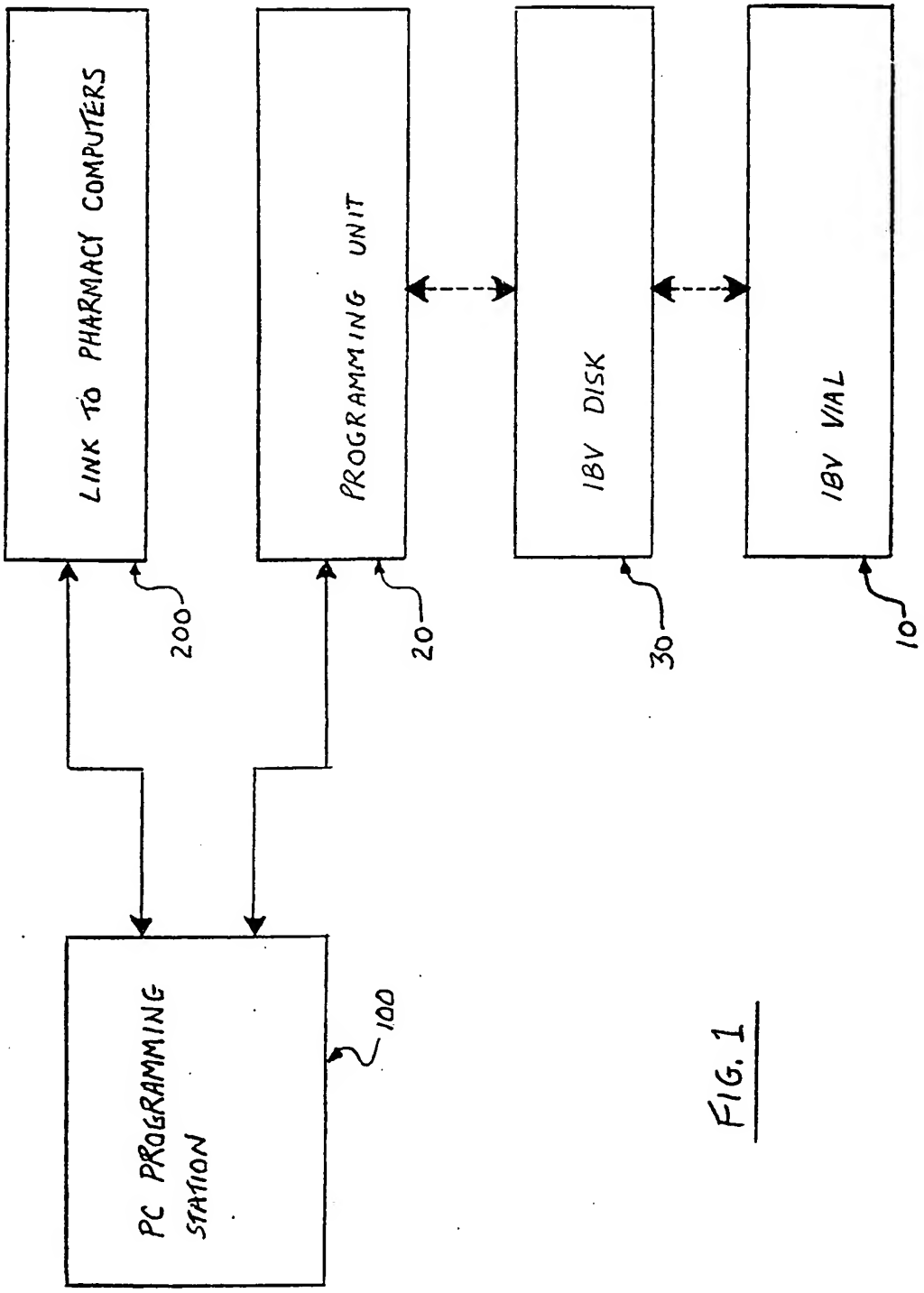

LINK TO PHARMACY COMPUTERS
PROGRAMMING UNIT
IBV DISK
IBV VIAL
PC PROGRAMMING STATION
200
20
30
10
100

FIG. 1

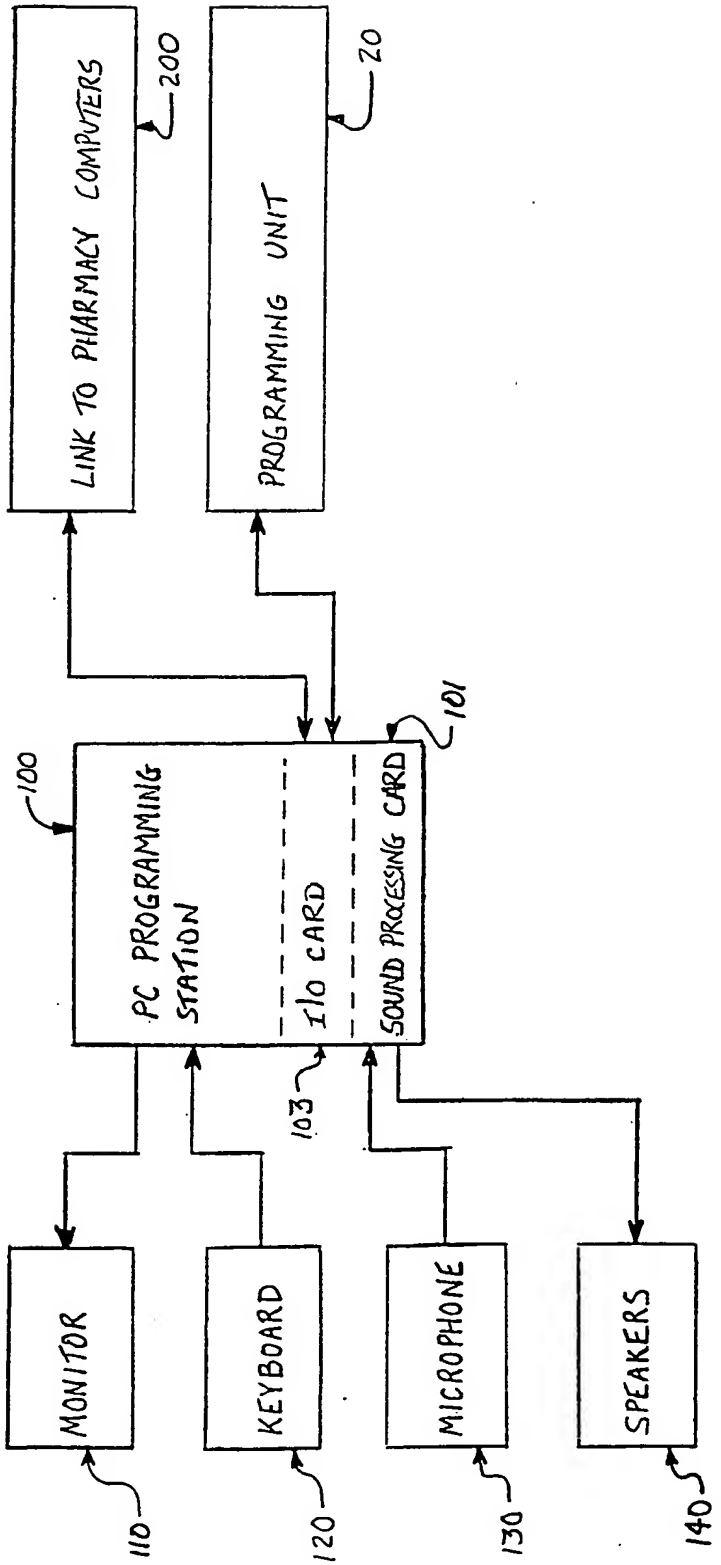

LINK TO PHARMACY COMPUTERS
200
PROGRAMMING UNIT
20
PC PROGRAMMING STATION
100
I/O CARD
SOUND PROCESSING CARD
101
103
MONITOR
KEYBOARD
MICROPHONE
SPEAKERS
110
120
130
140

FIG. 2

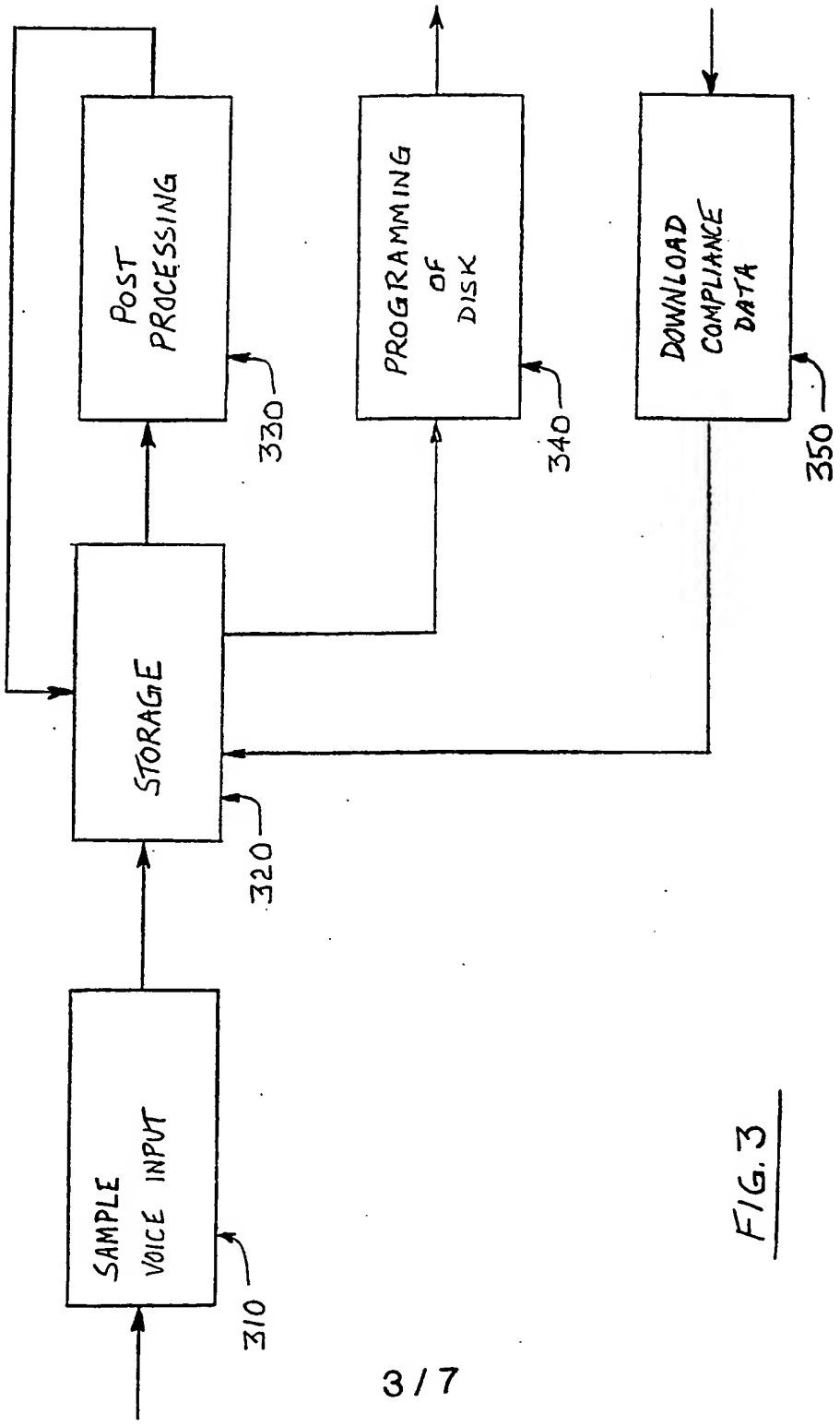

SAMPLE VOICE INPUT
310
STORAGE
320
POST PROCESSING
330
PROGRAMMING OF DISK
340
DOWNLOAD COMPLIANCE DATA
350

FIG. 3

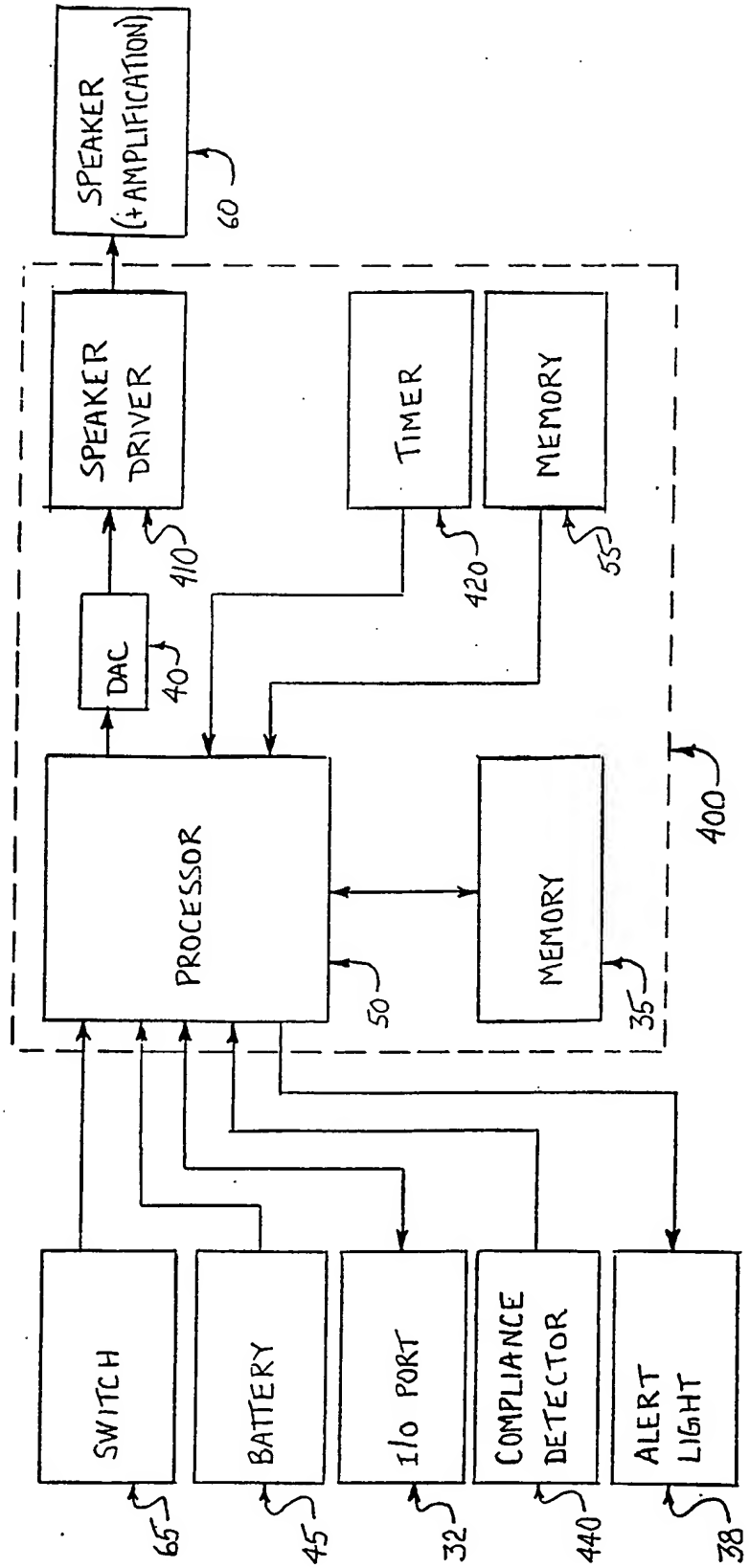

SPEAKER (+AMPLIFICATION)
60
SPEAKER DRIVER
410
TIMER
420
MEMORY
55
DAC
40
PROCESSOR
50
MEMORY
35
400
SWITCH
65
BATTERY
45
I/O PORT
32
COMPLIANCE DETECTOR
440
ALERT LIGHT
38

FIG. 4

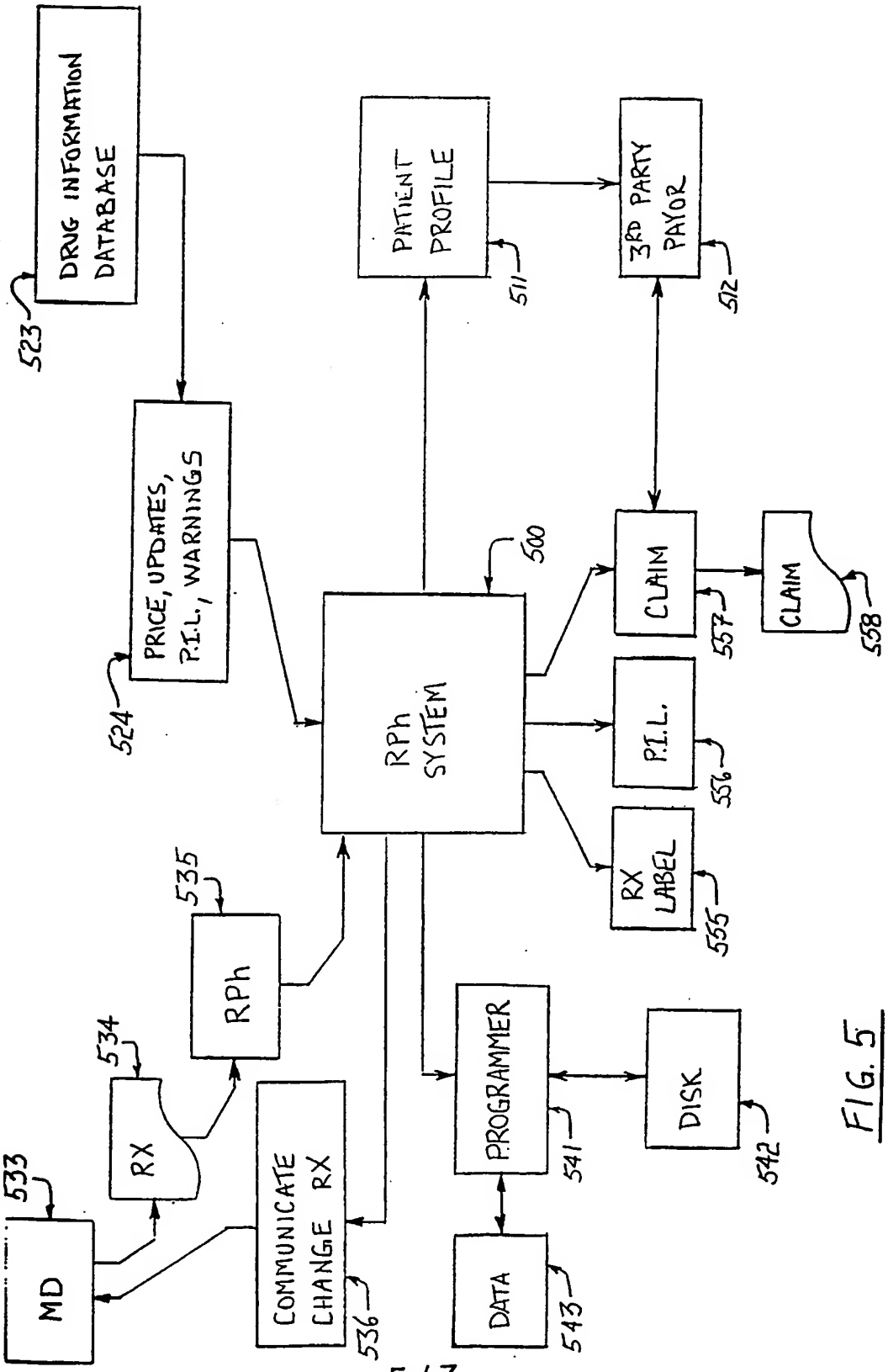
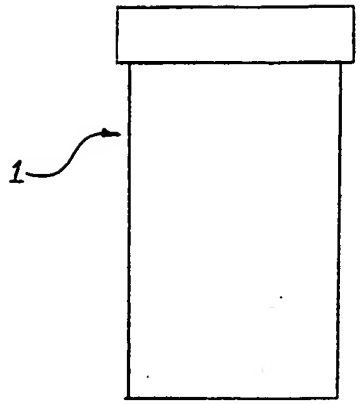

DRUG INFORMATION DATABASE
523
PATIENT PROFILE
511
3RD PARTY PAYOR
512
PRICE, UPDATES, P.I.L., WARNINGS
524
500
RPh SYSTEM
CLAIM
537
CLAIM
538
P.I.L.
536
RX LABEL
535
555
RPh
534
RX
PROGRAMMER
DISK
541
542
533
MD
COMMUNICATE CHANGE RX
536
DATA
543

FIG. 5



PRIOR ART

FIG. 6

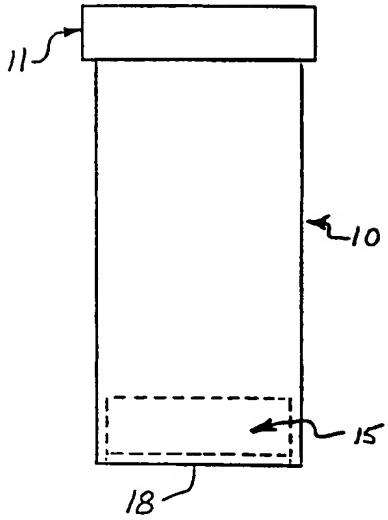


FIG. 7

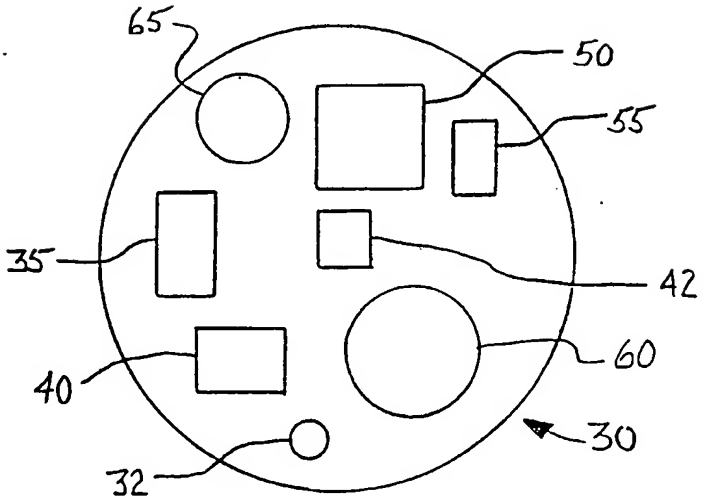


FIG. 8

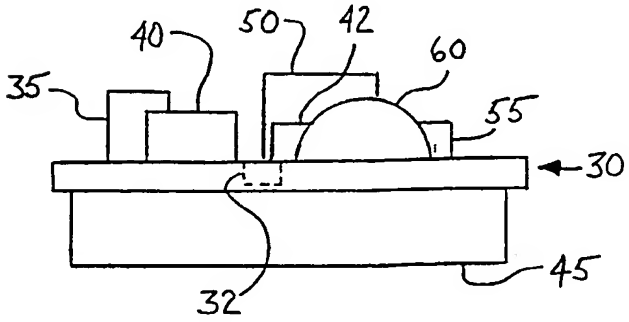


FIG. 9

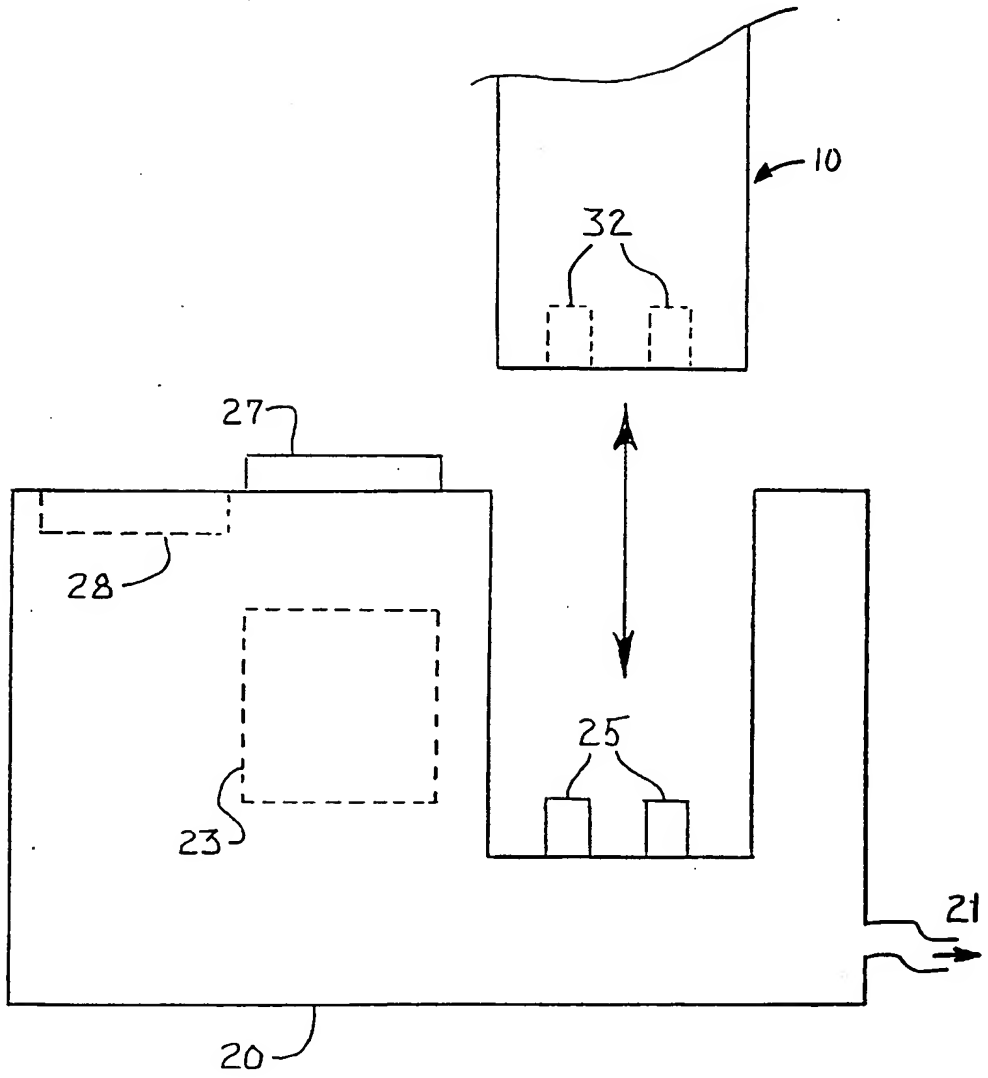


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03655

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :G06F 159:00
US CL :364/413.02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 364/413.02, 413.02, 413.03, 479, 569; 221/2, 3, 4, 5, 9, 10; 368/10, 109

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,837,719 (MCINTOSH ET AL) 06 JUNE 1989, figures 3 and 4 and their descriptions, particularly col. 11, lines 38-65, col. 13, lines 3-68.	1-18
Y	US, A, 5,148,944 (KAUFMAN ET AL) 22 SEPTEMBER 1992, figures 4a, 4b, 5, 6 and their descriptions, particularly col. 6, lines 6-44, col. 11, lines30-63.	1-18
Y	US, A, 4,962,491 (SCHAEFFER) 09 OCTOBER 1990, see entire document.	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
19 APRIL 1995

Date of mailing of the international search report
29 JUN 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
DONALD MCELHENY, JR.
Telephone No. (703) 305-3894

Form PCT/ISA/210 (second sheet)(July 1992)*